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Avance®

NEGATIVE PRESSURE WOUND THERAPY

User Guidelines for

Avance® Max / Avance® Flex

MÖLNLYCKE
HEALTH CARE

Distributed by
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Explanation of Label Symbols and Statements

Caution

Refer to instructions of use / booklet

North America ETL listed

Class II Equipment (Double Insulated)

Do not dispose of with the normal household waste

Manufacturer

Date of Manufacture

Fragile, handle with care

Caution: Federal (USA) law restricts this device to sale on or by the order of a licensed healthcare professional.

Keep dry

Protect from heat and radioactive sources

Temperature limitation

Humidity limitation

Atmospheric pressure limitation

Suitable for connection to type BF applied parts

Avance Max / Avance Flex Canisters are single use

WARNING This is a statement that alerts the user to the possibility of serious injury or other adverse reactions with the use or misuse of the device

CAUTION This is a statement that alerts the user to the possibility of a problem with the system associated with its use or misuse

IP22

IP: Ingress Protection (Pump only)

2: Protection against fingers or other object not greater than 80mm in length and 12mm in diameter

2: Protection from vertically dripping water when tilted to 15°)

Note: Abbreviation:

Negative Pressure Wound Therapy is abbreviated to '**NPWT**' throughout this document

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Introduction / Intended Use

Thank you for choosing to use the Avance Max / Avance Flex Negative Pressure Wound Therapy (NPWT) system from Mölnlycke Health Care. In doing so you have selected an efficient, competitively priced product for the treatment of many wounds including pressure ulcers, dehisced surgical wounds, diabetic/neuropathic ulcers, venous leg ulcers, post surgical wounds, sinus drainage and management, traumatic wounds and pre- and post-op flaps/grafts.

The Avance Max / Avance Flex NPWT system offers a choice of continuous or intermittent therapy modes and features a lightweight, versatile vacuum power unit which benefits from dual-power technology, offering a seamless choice of mains or battery operation. The integral battery is charge-optimised, and provides long-lasting power back-up when needed. The battery operation option allows the system to function away from a mains power supply for extended periods of time, allowing the patient full mobility during therapy, if required (optional carrying case with shoulder strap available).

NPWT is applied utilising a choice of Avance dressing kits (supplied separately) which include a single lumen transfer pad, a choice of acrylic transparent film or a transparent film with soft silicone adhesive and a polyurethane foam. Dressing kits are available in a range of sizes according to the wound type being treated.

Avance Max / Avance Flex NPWT system will benefit from careful installation and use, providing a long and effective service life. Please read and understand this document completely before applying NPWT.

CONTRAINDICATIONS

Do not place NPWT dressings directly in contact with exposed blood vessels, anastomotic sites, organs or nerves.

NPWT is contraindicated for patients with:

1. Malignancy in the wound
2. Untreated osteomyelitis
3. Non-enteric and unexplored fistulas
4. Wounds with difficult haemostasis
5. Necrotic tissue with eschar present

NOTE: After debridement of necrotic tissue and complete removal of eschar, NPWT can be used.

List of Components

Your Avance® Max / Avance® Flex NPWT system should comprise the following items - please ensure you have all of these before installation.

Note: Dressing kits are supplied separately.

- Avance® Max / Avance® Flex vacuum power unit
- 15V Mains adapter FW7362M/15 (Avance® Max only)
- 12V Mains adapter FW7556M/12 (Avance® Flex only)
- Avance® Max / Avance® Flex Canister (supplied fitted to power unit):
  - capacity 600ml (Avance® Max); 300ml (Avance® Flex)
- Avance® Canister Tubing 1.5 m

DRESSING KITS (supplied separately)

The pump is compatible with standard Avance® single lumen transfer pad foam dressing kits.

For dressing kit specific information, including additional warnings and precautions, see the Instructions for use for the Avance® dressing kit being used.

Note: Other dressing kits may be available; please contact Mölnlycke Health Care for latest information.

ALSO AVAILABLE

- 300ml*/600ml**/1200ml** canister with solidifier
- Y-connector
- Carrying case
- Bedside holder (Avance® Max only)
- IV pole attachment bracket (Avance® Max only)

* Avance Flex only
** Avance Max only

Cautions and Warnings

- There are no special skills required to operate the pump unit however, Negative Pressure Wound Therapy should only be used under the advice, recommendation and supervision of a licensed Physician and / or a registered nurse.
- The medical professional is responsible for applying his/her best medical judgment when using this system. Prior to use, the medical professional(s) treating the wound must assess how to best use the system for an individual wound.
- Select correct setting for therapy required. Care should be taken not to accidently change pressures once set as the efficiency of the therapy may be reduced. This could also be caused by pets, pests or children.
- The electricity supply is of the type indicated on the power adapter.
- Check the power adapter lead is free from damage and is positioned so as not to cause an obstruction, or injury, e.g. strangulation. Do not position the vacuum power unit or power adapter such that makes it difficult to disconnect the supply or drain plug.
- Ensure the power adapter lead, drain tube or vacuum power unit cannot become trapped or crushed, e.g. via raising or lowering of bed or bed rails or any other moving object. All tubes must be free of kinks, twists, properly connected and positioned so as not to cause an obstruction or injury.
- Do not place the vacuum power unit or power adapter on or near a heat source.
- Never use the power adapter whilst placed on top of or near to material which is flammable or can be damaged by heat. (The supplied power adapters plug directly into the power source partly mitigating this issue).
- The Avance® Max vacuum power unit must only be used with the approved power adapter supplied by Mölnlycke Health Care (see Specification on page 13)
- The Avance® Flex vacuum power unit must only be used with the approved power adapter supplied by Mölnlycke Health Care (see Specification on page 13)
- The Avance® NPWT system (Vacuum power unit and power adapter) is not used in the presence of flammable anesthetics or in an oxygen enriched environment.
- Suitable for continuous or intermittent use.
- Not suitable for sterilisation.
- The materials used in the manufacture of all components of the system comply with the required fire safety regulations.
- Mölnlycke Health Care advice against smoking whilst the system is in use, to prevent the accidental secondary ignition of associated items which may be flammable.
- Do not modify any of the medical devices or accessories in any way or use unspecified parts. Do not use unspecified parts.
- Choking may result from a child swallowing a small part that has become detached from the ME equipment.
- A dressing kit must be used with the Avance® Max / Avance® Flex system to carry out NPWT.

Cautions and Warnings (continued)

- Please refer to the dressing kit 'Instructions for Use' leaflet (supplied with dressing kit) for dressing application and setup. Note that the dressings in the set are sterile and for single patient / single use only, not intended for reuse.
- Intended for home healthcare and professional healthcare facility environments.
- The device is intended to be used with its carrying case or holder.
- Do not connect to any other medical device or equipment.
- When the canister is not fitted on the vacuum power unit, it is essential that the aperture on the rear face of the unit (Fig. 1) is not blocked or covered (e.g. with a label).
- The power unit and power adapter should be cleaned between patient use (refer to Care and Maintenance Section).
- The Avance® Max / Avance® Flex power unit battery is installed inside the unit and is not accessible by users. Battery replacement should only be carried out by qualified service personnel.

Figure shows Avance® Max.
Avance® Flex is similar.

- Wireless equipment such as mobile phones should be kept at least 10 feet or 3.3m away from this equipment.
- The above warnings, cautions and any safety considerations should be observed on a routine and regular basis, not only upon installation.

How to Apply NPWT

NB. A dressing kit must be used with the Avance® Max / Avance® Flex system to carry out NPWT (see page 3 for available options). Please refer to the dressing kit 'Instructions for Use' leaflet (supplied with dressing kit) for dressing application and setup.

CAUTION! The medical professional is responsible for using his/her best medical judgment when using this system. Prior to use, the medical professional(s) treating the wound must assess how to best use the system for an individual wound.

1. Remove all packaging from the power unit and mains adapter.
   Note: The power unit internal battery may be mostly discharged or in an inert state (Avance® Flex only) on first use. This will require the power unit to be used with the power adapter, which will automatically wake an inert battery (Avance® Flex only), operate the system and charge the internal battery.
2. If not already in place, attach canister to flat face of power unit by matching up the rear location pegs and rotating locking knob 1/4 turn clockwise to secure. Ensure canister is correctly located and secured otherwise NO CANISTER message will appear and power unit will not operate.
3. Prepare and seal wound as described in dressing kit 'Instructions for Use'.

How to Apply NPWT (continued)

4. Attach dressing kit to the Avance® Max / Avance® Flex power unit canister by lining up locator stud on the tubing connector with the notch on the canister tubing port located on top corner of canister, pushing down gently and twisting clockwise to lock. A tube guide is fitted to assist with the routing of the tubing.

5. OPERATING THE VACUUM POWER UNIT:

a) If using the mains, insert the smaller end (DC outlet) of the supplied power adapter cable into the side of the Avance® Max / Avance® Flex power unit, and the other end into the appropriate power outlet. The power adapter indicator should be illuminated.

NB. The battery will charge when the unit is connected to the power source (indicated by battery charge status icon on display screen scrolling from left to right) and provides automatic power back-up if the external power supply or adapter fails. It is recommended to use the power adapter when convenient to do so as this will ensure the battery is fully charged when needed. A fully discharged battery will take a number of hours to fully charge.

b) Press RUN/STOP button to invoke and display stand-by mode (the power unit will beep and therapy mode, operating pressure and battery charge status will be displayed).

c) When new from production, the power unit will default to continuous therapy mode at 120mmHg. In all other cases, the unit will default to previous pressure and therapy mode settings. To switch between continuous and intermittent therapy modes, press the THERAPY MODE button until power unit beeps to confirm change of mode. Adjust vacuum level if required using the UP and DOWN arrow buttons.

d) Press RUN/STOP button again to initialise and run the power unit.

NB. Vacuum level and therapy mode can be adjusted when in stand-by mode and for up to 1 minute after power unit is running. Power unit will automatically lock 1 minute after last button operation when running to prevent inadvertent operation of button functions (except MUTE), as indicated by 🔒 on the display screen. Press and hold the UNLOCK button until power unit beeps if further button operation is needed. Display screen is only illuminated for a short period after button operation in battery mode.

6. Once the power unit is running, observe the wound site. The dressing should contract noticeably, becoming firm to the touch. If the dressing fails to contract, the dressing has not been completely sealed. Reinforce the dressing seal and/or adjust the drain and initiate suction again.

⚠ WARNING: Particularly when used outside of a medical institution, get immediate medical assistance from those responsible for the prescription and setting of the NPWT system should any of the following occur:- obvious bleeding or pain; the wound site or exudate presents unexpected changes in its condition, colour or odour; the wound dressing becomes detached or ineffective; the tubing becomes blocked.

7. To change or remove dressing, unlock power unit (press and hold UNLOCK until power unit beeps), then press the RUN/STOP button until power unit beeps three times and switches off. Clamp canister tubing and remove by turning anticlockwise and lifting out of tubing port on canister. Dispose of used dressing kit according to local clinical waste policy. If required, apply new dressing kit and continue NPWT.

How to Apply NPWT (continued)

8. Canisters should be replaced as required or weekly. To change canister, make sure power unit is switched off (if still running, press and hold the UNLOCK button, followed by the RUN/STOP button). Clamp canister tubing and remove by turning anticlockwise and lifting out of tubing port (this can be reconnected to new canister and unclamped if wound dressing is not being changed). Remove sealing plug from its location on top corner of canister and use to cap tubing port to seal in contents. Rotate locking knob 1/4 turn anticlockwise and remove canister. Dispose of used canister according to local clinical waste policy. If continuing NPWT, attach new canister and connect canister tubing as previously described.

9. To stop the power unit, press and hold the UNLOCK button until power unit beeps and 🔒 clears from display screen. Then press the RUN/STOP button until power unit beeps three times and switches off.

10. Place the user manual in a safe place for future use.

User Information

- The Avance® Max / Avance® Flex power unit will automatically lock 1 minute after last button operation when running to prevent inadvertent operation of button functions (except MUTE), as indicated by 🔒 on the display screen. Press and hold the UNLOCK button until power unit beeps if further button operation is needed (i.e. change of therapy mode or vacuum level, or switching off power unit). The power unit will lock again 1 minute after last button operation.

  Please note that when running, the Avance® Max / Avance® Flex power unit must be unlocked before it can switched off, i.e. the power unit cannot be switched off when the 🔒 is displayed on the screen.

- During operation, the power unit should be placed upright on a horizontal surface with the display uppermost. The Avance® Max power unit can be placed in the optional metal holder for use at the bedside or attached to an IV pole using the optional bracket. The Avance® Flex is supplied with a bracket for IV pole attachment. In all instances the power unit/canister assembly should be kept upright during use to ensure correct operation. The Avance® Flex will display a warning if the unit is over tilted.

User Information (continued)

BUTTON FUNCTIONS

RUN/STOP
Press to invoke stand-by mode prior to running power unit.
Press again to run power unit. Press whilst power unit is running (and unlocked) to cease operation and switch of the unit.

VACUUM LEVEL
Vacuum level can be adjusted when in stand-by mode and for up to 1 minute after last button operation when power unit is running using the UP and DOWN arrow buttons. Pressure can be adjusted in 5mmHg increments between 60mmHg and 180mmHg according to treatment requirements. The power unit will begin operation at the previous stored pressure. The selected vacuum level is shown on the display screen.

THERAPY MODE
The Avance® Max / Avance® Flex power unit offers a choice of continuous or intermittent therapy modes. To switch between therapy modes, press the THERAPY MODE button until power unit beeps to confirm change of mode. When in intermittent therapy mode, the power unit will provide vacuum therapy for periods of 5 minutes followed by a 2 minute rest period. The selected therapy mode is displayed on the power unit screen and can be altered in either stand-by or (unlocked) run modes.

MUTE
Press to silence the sounder and to clear the message from the display screen. The MUTE button can also be used to force power-off in stand-by mode.

UNLOCK / LIGHT
The Avance® Max / Avance® Flex power unit will automatically lock 1 minute after last button operation when running to prevent inadvertent operation of button functions (except MUTE), as indicated by on the display screen. Press and hold the UNLOCK button until power unit beeps if further button operation is needed (i.e. change of therapy mode or vacuum level, or switching off power unit). The power unit will lock again 1 minute after last button operation.
Pressing this button will also illuminate the display screen for 10 seconds if power unit is in battery operation (screen will always be illuminated in mains operation).

USER SELECTABLE FUNCTIONS (Avance® Flex Only)

The following functions are selectable in a user menu:

- Language selection
- Tilt indicator, switch on or off
- Tube constriction indicator, switch on or off
- Battery inert. **Note that it is essential that the battery is put to this condition before international transportation.**

User Information (continued)

The menu is accessed by a three second press of the unlock key when in the stand-by mode. The arrow key scrolls to the functions shown above, and the mode select key allows the function to be toggled on or off, or selected. For language selection, press and hold the mode key until the required language is displayed. Releasing the mode key will then set the display for the language. Pressing the unlock key returns the device to stand-by mode.

IV POLE ATTACHMENT

An IV pole attachment bracket is available as an optional accessory for the Avance® Max. Instructions for its use are included with the part.

Battery Information

- A fully charged battery should operate the power unit continuously for at least 24 hours.
- Charge status is shown on the display of the power unit when it is in stand-by and run mode.
- As the batteries are automatically charged as required when the system is operating on mains power, the battery module should not require removing or changing in normal use.
- Use only the mains adapter supplied with the system.
- When power unit operation times when running from the internal battery are noticeably shorter than normal, it is time to replace the battery pack. Contact Mölnlycke Health Care or authorised dealer for battery replacement service.
- Never use any battery pack that is damaged or worn out. Use the battery pack only for its intended purpose.
- The battery pack is not serviceable and should be replaced if faulty (indicated by applicable battery faults displayed in place of battery charge status icon). Contact Mölnlycke Health Care or authorised dealer for battery replacement service.
- **For Avance® Flex only:** The internal Lithium Ion Battery may be received or become inert if left for extended periods in storage or a fully discharged condition. Connection a power adapter will wake / charge the battery and immediately allow the full use of the vacuum power unit. It is possible to force the vacuum power unit into making the battery inert should this be required by some airline and other carriers. See 'User Selectable Functions' Menu for details (Page 8).

Battery Information (continued)

CHARGING THE BATTERY

If not fully charged, the battery will automatically charge when the power unit is plugged into a power source via the power adapter. The battery will charge whilst the vacuum power unit is in standby or a run mode.

REPLACING THE BATTERY

The battery is installed inside the unit and is not accessible by users. Battery replacement should only be carried out by qualified service personnel. Contact Mölnlycke Health Care or authorised dealer for battery replacement service.

Care and Maintenance

POWER UNIT

Always disconnect the Avance® Max / Avance® Flex power unit from the power adapter and the power adapter from the power source before carrying out maintenance, repairs, servicing or cleaning. Check all electrical connections and power lead for signs of excessive wear. The power unit / power adapter can be wiped down with detergent or disinfectant solution or wipe*. Do not use solvents. Unsuitable for sterilisation. Dispose of the power unit / power adapter in accordance with the local regulations including WEEE requirements. The power unit / power adapter should be cleaned between patient use as a minimum.

* In line with the MHRA Medical Device Alert (MDA/2013/019), Mölnlycke Health Care advises customers to use pH neutral, high level disinfectant cleaning products to sanitise reusable medical devices to prevent damage to materials and the degradation of plastic surfaces after prolonged use. The use of inappropriate cleaning and detergent materials on medical equipment could damage surfaces and may compromise the ability to decontaminate medical devices adequately or may interfere with device function.

DRESSING KITS AND CANISTERS

Dressing kits and canisters are disposable and intended for single use only. After use please dispose of in an appropriate manner in accordance with local regulations and hospital best practice.

SERVICING

Mölnlycke Health Care recommend that all power units should be serviced every year or as indicated by the 'hours to service' display. The unit contains no user serviceable parts and should only be serviced by either Mölnlycke Health Care or an authorised dealer. Mölnlycke Health Care will make available on request service manuals, component parts lists and other information necessary for Mölnlycke Health Care, an authorised dealer or a competent electrical engineer to repair or service the system. For service, maintenance and any questions regarding this, or any other product, please contact Mölnlycke Health Care.

Care and Maintenance (continued)

It is the customer's responsibility to ensure the following prior to collection:

- the system is cleaned of any obvious contaminants.
- contamination status is documented.
- assistance is given to Mölnlycke Health Care personnel to bag the equipment if the device has been in a known or suspected infectious environment.

TRANSPORT AND STORAGE

- Handle with care. Please report instances of damage or impact to Mölnlycke Health Care.
- Transport
- –25 °C without relative humidity control; and
- +70 °C at a relative humidity up to 93 %, non-condensing.
- An atmospheric pressure range of 700 hPa to 1 060 hPa.
- Suitable for all standard modes of transport when in the correct packaging.

OPERATIONAL CONDITIONS

- A temperature range of +5 °C to +40 °C;
- A relative humidity range of 15% to 93%, non-condensing
- Operational Atmospheric Pressure: 700 hPa to 1060 hPa
- Suitable for pollution degree 2
- Operational altitude ⩽ 2 000 m
- IP Rating: IP22 pump only

MANUFACTURER's GUARANTEE

All power units are covered by a 24 month manufacturer's guarantee. The intended design life is 5 years if fully serviced.

Warning and Fault Indicators

All sounders can be silenced and messages cleared by pressing the MUTE button once. Alarm will self-clear if unit returns to normal run mode. Alarm can be cancelled by mute button but fault will reappear if problem not resolved.

If fault remains/re-occurs, contact Mölnlycke Health Care.

WARNING INDICATORS

NO CANISTER – indicates canister is missing or is not correctly fitted. The power unit will fail to operate whilst this message is displayed. Check that canister is correctly located and secured, as detailed on page 5.

NO BATTERY (Avance® Max only) – indicates battery is not correctly fitted. The power unit will only operate using the power adapter whilst this message is displayed. Contact Mölnlycke Health Care or authorised dealer to check battery and installation.

LOW BATTERY (only appears during battery operation) – the power unit will continue to run whilst this warning is displayed. Press the MUTE button to silence the sounder and clear the message. Note that the system will automatically shut down when the battery is fully discharged. Plug into a power source to charge.

Warning and Fault Indicators (continued)

CANISTER FULL – indicates that the canister has reached its capacity and should be changed. The power unit will cease to run and the message/sounder will continue until the RUN/STOP button is pressed or the canister is removed, both of which cancels the message and sounder and returns the power unit to stand-by mode. Change canister as detailed on page 7.

NB. The 'Canister Full' sounder can be silenced by pressing the MUTE button, however if the canister is not removed/changed the sounder will reoccur after 10 minutes.

LEAK DETECTED – indicates vaccum pressure has fallen below minimum allowable levels. Power unit will continue to run whilst these messages is displayed. Check that wound dressing is completely sealed and that all tubing connections are secure. Press the MUTE button to silence the sounder and clear the messages. The sounder will become silent and the message will disappear automatically when the fault condition ceases. If fault re-occurs, contact Mölnlycke Health Care.

BLOCKAGE – indicates that pump demand has abruptly ceased. Note that a certain level of flow in the drain is required for the indicator to be active. The message will occur for example in the case of a blocked tube, kinked tube or if the dressing is obstructed. Note that the tube constriction indicator can be selected on or off as required (see 'User Selectable Functions' on page 8). Default is on. The sounder will become silent and the message will disappear automatically when the fault condition ceases.

TILT (Avance® Flex only) – activates when the device is in active mode and is placed at an angle that could affect the canister full indication. The sounder delays for 5 seconds, and is self-muting when the unit is returned to an upright position. Note that the tilt indicator can be selected to be on or off as required (see 'User Selectable Functions' on page 8). Default is on.

FAULT INDICATORS

EMI Fault – indicates that the unit detects the pressure sensor amplifier is adversely affected by external RF fields. The power unit will continue to run whilst this message is displayed. Press the MUTE button to silence the sounder. This indicator will clear when interference ceases.

CHECK MOISTURE (Avance® Flex only) – indicates that moisture or exudate has been detected in the power unit. The power unit will cease to operate on this indication. Refer to Mölnlycke Health Care for service assistance.

O/C Batt or CCT Fail (Avance® Max only) – will appear instead of battery charge status icon) – indicates that the battery is not functioning correctly and cannot be used. The power unit will only operate using mains power whilst this message is displayed. Contact Mölnlycke Health Care to order a replacement battery.

If any of the following faults are displayed the power unit will cease to operate:- PUMP OPEN; NO CANISTER; PUMP OFF FAULT (PUMP SHORT); RELEASE KEY; BATTERY FAULT (Avance® Flex only). Should any of these faults occur, press the MUTE button to reset the power unit. If fault remains/re-occurs, contact Mölnlycke Health Care.

The Avance® Max/Avance® Flex power unit may also display the following information (the power unit will continue to run whilst these messages are displayed):

- Service due - Contact Mölnlycke Health Care to arrange service
- Uncalibrated - Contact Mölnlycke Health Care for recalibration

Specification

POWER UNIT		Avance® Max	Avance® Flex
Model Ref:		Avance Max 7703000	Avance Flex 7702000
Construction:		Flame retardant ABS	Flame retardant ABS
Dimensions:		210mm x 205mm x 105mm	161mm x 155mm x 90mm
Weight:		2.2 kg	1.0 kg
DC Input Voltage:		15V Nominal	12V Nominal
Vacuum Application:		Continuous (default therapy) or intermittent	Continuous (default therapy) or intermittent
Pressure Range:		60 to 180mmHg (+0mmHg / -20mmHg)	60 to 180mmHg (+0mmHg / -20mmHg)
Fixed Internal Battery:		6V 2.5Ah NiMH	3.7V 10Wh Lithium Ion Rechargeable Cell
CANISTER			
Construction:		ABS Trans smoked grey, textured (includes 1 x 8g dissolvable sachet of desiccant)	
Capacity:		600ml or 1200ml	300ml
Dimensions:	300ml	n/a	156mm x 163mm x 32mm
	600ml	200mm x 190mm x 35mm	n/a
	1200ml	200mm x 190mm x 70mm	n/a
POWER ADAPTER			
Mains Adapter Type:		FW7362M/15 (supplied)	FW7556M/12 (supplied)
Input:		100-240V / 50-60Hz / 700mA	100-240V / 50-60Hz / 400mA
Output:		15V dc / 2A	12V dc / 1.5A
Cable Length:		4 metres	4 metres
Part Number:		7703006	7702006

The above mains adapters are considered part of the ME equipment

The Avance® Max / Avance® Flex power units must only be used with the specific external power adapters as supplied by Mölnlycke Health Care.

These products are manufactured by Talley and distributed by Mölnlycke Health Care. Talley products are manufactured to comply with International and National safety standards. Talley design and manufacture products to conform to the requirements of ISO9001, ISO13485 and Directive (93/42/EEC).

Mölnlycke Health Care reserves the right to modify the specification of any product without prior notice in line with a policy of continual product development.

EMI/EMC Statement and Manufacturer's Declaration

This equipment has been tested and found to comply with the limits of EN 60601-1-2.

These limits are designed to provide reasonable protection against harmful interference in both a medical and residential environment. This equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with manufacturer's instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception or other equipment, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment.
- Connect the equipment to an outlet on a circuit different from that to which the receiver or equipment was connected.

The equipment having been tested to operate within the limits of electromagnetic compatibility. (Immunity to interference from nearby sources radiating radio frequency energy). Sources exceeding these limits may give rise to operation faults. Where possible the system will sense the interference and if it is of short duration transparently take countermeasures whilst operating near normally, or failing this will issue a warning and take measures for the continued safely of the user. Further increased levels of energy may cause the system to stop operating, continuously generate random faults or continuous resets.

Try to ascertain the source of the interference by turning nearby or suspect equipment off, and see if the interference effects stop. In any such event the user is encouraged to try to correct the interference by one of the following measures:

- Have the interfering equipment repaired or replaced.
- Reorient or relocate the interfering equipment.
- Increase the separation between the equipment and the possible source of the interference.
- Connect the equipment to an outlet on a circuit different from that to which the interfering equipment was connected.

Information regarding Electro Magnetic Compatibility (EMC) according to IEC60601-1-2

With the increased number of electronic devices such as PC's and mobile telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. The EMC (Electro Magnetic Compatibility) standard IEC60601-1-2 defines the levels of immunity to these electromagnetic interferences. From the other hand, medical devices must not interfere with other devices. IEC60601-1-2 also defines the maximum levels of emissions for these medical devices. The Avance® Max / Avance® Flex conforms to this IEC60601-1-2 standard for immunity and emission. Nevertheless, special precautions need to be observed:

- The Avance® Max / Avance® Flex needs to be installed and put into service according to the EMC information below.
- The Avance® Max / Avance® Flex is intended for use in the electromagnetic environment specified in the tables below. The user of the Avance® Max / Avance® Flex should assure that it is used in such environment.
- In general, although the Avance® Max / Avance® Flex complies to the EMC standards, it can be affected by portable and mobile RF communications equipment (such as mobile telephones).
- The Avance® Max / Avance® Flex should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the Avance® Max / Avance® Flex should be observed to verify normal operation.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions (IEC 60601-1-2)		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Class B	The Avance® Max / Avance Flex systems are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage pump supply network that supplies buildings used for domestic purposes.
Harmonics emissions 61000-3-2	Class A	
Voltage fluctuations / flicker emissions 61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV For mains supply lines ± 1kV For input/output lines	± 2 kV For mains supply lines ± 1kV For input/output lines	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment.
Surge IEC61000-4-5	± 1kV line(s) to line	± 1kV line(s) to line	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on mains supply IEC 61000-4-11	<5%Ur (>95%Ur) for 0.5 cycle	<5%Ur (>95%Ur) for 0.5 cycle	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment. In the event of a mains interruption the Avance® Max / Avance Flex system will automatically use internal battery power, unless the battery is exhausted.
	40%Ur (60% dip in Ur) for 5 cycles	40%Ur (60% dip in Ur) for 5 cycles	
	70%Ur (30% dip in Ur) for 25 cycles	70%Ur (30% dip in Ur) for 25 cycles	
	>5%Ur (>95% dip in Ur) for 5 secs	>5%Ur (>95% dip in Ur) for 5 secs	
Mains frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Mains frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
Note: Ur is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V rms 150 kHz ~ 80 MHz 3 V/m 80 MHz ~ 2.5 GHz	3 V rms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Avance® Max / Avance Flex including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Note1: At 80 MHz and 800 MHz, the higher frequency range applies. Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Avance® Max / Avance Flex is used exceeds the applicable RF compliance level above, the Avance® Max / Avance Flex should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Avance® Max / Avance Flex.

[b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the Avance® Max / Avance Flex

The Avance® Max / Avance Flex is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Avance® Max / Avance Flex can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Avance® Max / Avance Flex as recommended below, according to the maximum output power of the communications equipment.

Output Power of Transmitter in Watts (W)	**Separation distance according to frequency of transmitter in Meters (m)**		
	150 kHz to 80 MHz d = 1.2 √P	**80 MHz to 800 MHz d = 1.2 √P**	**800 MHz to 2.5GHz d = 2.3 √P**
0.01	0.01	0.01	0.01
0.12	0.12	0.12	0.12
0.12	0.12	0.12	0.12
0.23	0.23	0.23	0.23
0.1	0.1	0.1	0.1

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in Meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer. Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

This medical device is compliant with:

IEC 60601.1 3rd edition Medical electrical equipment safety and essential performance

IEC 60601.1.11 2010 Home healthcare environment

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